REMARKS

Claims 144, 156-168 and 170-210 are pending. Claims 211-231 have been cancelled. Claims 144, 156-158, 178, 180 and 186-187 have been amended. Support for the amendments to the claims can be found throughout the application as originally filed. No new matter has been added.

Applicant thanks the Examiner for the telephone interview with Applicant's attorneys on March 5, 2005 during which the Examiner agreed to enter the amendments to the claims, the terminal disclaimer, and the Declaration Under 37 CFR §1.132 of Abbie Celniker, Ph.D.

Rejection of Claims 144-168, 170-177 and 180-231 Under 35 U.S.C. §101

Claims 144-168, 170-177 and 180-231 are rejected under 35 U.S.C. §101 as not being "sufficiently distinguished over antibodies as they exist naturally because the claims do not particularly point out any non naturally occurring differences between the claimed products and naturally occurring products." Claims 144, 156-158, 186 and 187 have been amended to recite that the antibody or antigen binding portion thereof is an "isolated" antibody or antigen binding portion thereof. This obviates the rejection of these claims.

The remaining claims are directed to an antibody or antigen binding portion thereof that is bound to a cytotoxic drug or label or that is part of a pharmaceutical composition or kit. These antibodies (or antibody fragments) are clearly distinguishable over antibodies found in nature. For example, claims 159-168, 170, 171, 184-185, 188-193, 196-203 and 208-210 are directed to antibodies (or antibody fragments) bound to various cytotoxic drugs. Claims 172-177, 194 and 195 are directed to antibodies (or antibody fragments) bound to a label. Claims 181-183 and 204-207 are directed to kits that include the labeled antibodies (or fragments thereof) and means to detect the label. Claim 180 is directed to a pharmaceutical composition that includes the antibody (or antibody fragment) and a pharmaceutically acceptable carrier, excipient or stabilizer. It is clear that the antibodies (and fragments thereof) coupled to labels or cytotoxic drugs, and these antibodies (or antibody fragments) as part of kits and pharmaceutical

compositions, include limitations which clearly distinguish them from antibodies as the exist in nature.

Lastly, claims 178 and 179 are directed to an isolated cell. Since these claims recite an "isolated" cell, it is clear that this is not a cell as it exists in nature.

For the reasons discussed above, Applicant respectfully requests that the Examiner withdraw this rejection.

Obviousness-Type Double Patenting Rejection of Claims 144, 156-168 and 170-231

Claims 144, 156-168 and 170-231 are rejected "under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-109 of US Patent No. 6,649,163."

A terminal disclaimer is being filed herewith, thereby obviating this rejection.

Rejection of Claims 144, 156-168 and 170-231 Under 35 U.S.C. §112, first paragraph

Claims 144, 156-168 and 170-231 have been rejected under 35 U.S.C. §112,first paragraph, "as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." Specifically, the Examiner asserts that the instant disclosure "does not contemplate nor provide support for the presently claimed antibodies because they do not appear to contemplate nor suggest the discovery screening, and or use of antibodies that compete or bind the same epitope as the monoclonal antibodies J415, J591, J533, and E99."

Applicant respectfully traverses this rejection. However, in the interest of expediting prosecution of the present application, the claims have been amended to remove the recitation of antibodies or antigen binding portions thereof that bind to an epitope which is also recognized by a monoclonal antibody selected from the group consisting of E99, a J415, a J533, and a J591. The claims are directed to an antibody or antigen binding portion thereof which competes for binding to PMSA with a monoclonal antibody selected from the group consisting of an E99, a

J415, a J533, and a J591 monoclonal antibody. The Examiner has also rejected claims containing this language.

The application clearly provides sufficient description of antibodies that compete for binding to PSMA with the recited antibodies such that a skilled artisan would recognize that Applicant was in possession of the claimed invention at the time of filing.

The written description requirement is met if the specification shows that an applicant was in possession of the claimed invention at the time of filing. "When the original specification accomplishes [this], regardless of *how* it accomplishes it, the essential goal of the description requirement is realized." *In re Smith*, 481 F.2d 910, 914 (CCPA 1973). It is well accepted that "in order to satisfy the written description requirement, the disclosure as originally filed does not have to provide *ad haec verba* support for the claimed subject matter at issue". *Purdue Pharma v. Faulding, Inc.*, 56 USPQ 2d 1481 (Fed. Cir. 2000); and MPEP § 2163.02. As provided, for example, in *In re Wright*, 866 F.2d 422 (Fed. Cir. 1989), "the fact...that the exact words here in question...are not in the specification is not important" (emphasis added). In *Wright*, the claims at issue involved methods for forming images and included a step of depositing a layer of microcapsules in the form of a free flowing powder. The claims recited that the layer of microcapsules was "not permanently fixed". The Examiner rejected claims with this language, asserting a lack of written description. On appeal, the Federal Circuit held that the original specification unequivocally taught the absence of permanently fixed microcapsules, as demonstrated by a description of the removal of microcapsules from the surface and a warning that the capsules should not be disturbed prior to the formation of the image, and that the written description rejection "was clearly erroneous".

Here, the claimed invention involves an antibody having a specific feature: it competes for binding PSMA with a specific, disclosed antibody, namely E99, J591, J415 or J533. The support for this language in the specification of the above-identified application is even clearer than the situation presented in *Wright*. As provided in the Declaration of Abbie Celniker under 37 CFR § 1.132 (hereafter "the Declaration", filed herewith), one of ordinary skill in the art at the time the application was filed would have found that the specification discloses and that

Applicant was in possession of antibodies that compete for binding with one of the specifically disclosed antibodies. Specifically, the Declaration points to page 27 lines 26-35 of the specification of the above-identified application as filed. This passage discusses a particular embodiment wherein antibodies are used to direct two components to a desired site, and provides as follows:

> ***a first biological agent*** is conjugated with a prodrug which is activated only when in close proximity with a prodrug activator. The prodrug activator is conjugated with ***a second biological agent according to the invention, preferably*** one which binds to a non-competing site on the prostate specific membrane antigen molecule. Whether two biological agents bind to competing or non-competing binding sites can be determined by conventional competitive binding assays. (***emphasis added***).

From the passage recited above, it would be clear to one of ordinary skill in the art at the time the application was filed that the cited text, in combination with the rest of the specification, discloses two types of antibodies --those that compete for binding with an antibody "according to the invention" and those that do not compete for binding with an antibody "according to the invention", the later being preferred in the particular embodiment being described. But whether preferred or not, it is clear from the text that Applicant was in possession of the idea of an antibody which competes for binding with an antibody according to the invention. The text also provides, see, e.g., the last sentence of the quoted passage, what constitutes a competing site and a non-competing site by stating that "whether two biological agents bind to competing or non-competing sites can be determined by conventional competition binding assays." Therefore, the application necessarily discloses the concept of an antibody that competes for binding with an antibody according to the invention. Thus, a person of ordinary skill in the art at the time the application was filed would have believed that the concept of having an antibody that competes for binding with "an antibody according to the invention" is necessarily part of the disclosure of the present application and that Applicant was in possession of this element of the invention at the time of filing.

As provided in the Declaration, it is also clear that, upon reviewing the specification of the above-referenced application, one of ordinary skill at the time the application was filed,

would have believed that monoclonal antibodies E99, J415, J533 and J591 are "antibodies according to the invention." These four antibodies are disclosed throughout the application as being antibodies of the invention. In fact, the very next sentence, at page 28, lines 1-6, after the passage recited above states as follows:

> For example, monoclonal antibodies J591, J533, and E99 bind to competing binding sites on the prostate specific membrane antigen molecule. Monoclonal antibody J415, on the other hand, binds to a binding site which is non-competing with the site to which J591, J533, and E99 bind.

Thus, the application necessarily discloses that monoclonal antibodies E99, J415, J533 and J591 are antibodies according to the invention. Given that J415, J591, J533 and E99 are antibodies of the invention, and that the specification clearly supports the concept of antibodies that compete for binding with an antibody of the invention, a skilled artisan would recognize that the application discloses and that Applicant was in possession of antibodies that compete for binding with J415, J591, J533 or E99. The text of the specification describes and shows possession of the claimed subject matter.

For the reasons discussed above, Applicant respectfully requests that the Examiner withdraw this rejection and allow all the currently pending claims.

Enclosed is a check for the Petition for Extension of Time fee. Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: 3/16/05

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